

REMARKS

This is a response to the non-final Office Action mailed on May 31, 2011. No fee is due in connection with this response. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-1345 on the account statement.

Claims 1-3 and 5-11 are currently pending. Claims 3 and 6-7 were previously canceled without disclaimer. In the Office Action, Claims 1-11 are rejected under 35 U.S.C. §103. In response, Claims 1 and 8-9 have been amended, Claims 5 and 9 have been canceled without disclaimer, and Claims 12-14 have been added. These amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejection should be reconsidered and withdrawn.

In the Office Action, Claims 1-3, 5 and 8-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2001/0014322 to Chen ("*Chen*") in view of the printed publication to Brody ("*Brody*") and further in view of U.S. Patent No. 7,374,753 to Farmer et al. ("*Farmer*"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

Independent Claim 1 has been amended to recite, in part, a method for treating the effects of infection by enterotoxin-producing pathogens comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of a meat peptone and about 0.3% to about 7% by volume of a meat extract. The amendment is supported in the specification at, for example, page 4, line 37-page 5, line 8.

As taught by Applicants' specification, the term "peptone" means any soluble mixture of products produced by the partial enzymatic or acid hydrolysis of proteinaceous material. In this regard, a meat peptone has a meat protein as the protein starting material. For example, a meat peptone is an enzymatic digest of animal tissue.

As taught by Applicants' specification, the term "meat extract" is intended to cover extracts of any meat, such as beef, pork, lamb, chicken and/or turkey, among others. It may also be from a mixture of the above-cited meats. In any event, it can provide at least nitrogen, amino acids, and carbon.

Applicants have surprisingly found that by ingesting meat extracts together with meat peptones, individuals suffering from infection by pathogens as evidenced by intestinal disorders such as, for example, failure of gut epithelial integrity and diarrhea, have a normalized fluid secretion, a cellular structure less damaged, and a decreased inflammation compared to individuals having the same disorders, but a diet not supplemented with meat extracts or peptones. See specification, page 5, lines 20-25, and Examples 1-2.

Applicants respectfully submit that the cited references alone or in combination fail to disclose or suggest each and every element of independent Claim 1. Specifically, *Chen*, *Brody* and *Farmer* alone or in combination fail to disclose or suggest methods for treating the effects of infection by enterotoxin-producing pathogens comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of a meat peptone and about 0.3% to about 7% by volume of a meat extract as required by independent Claim 1.

Chen discloses a microbe composition comprising three viable and beneficial lactic acid producing bacteria of new strains: *Bifidobacterium bifidum* 6-1, *Lactobacillus acidophilus* YIT 2004 and *Streptococcus faecalis* YIT 0027. *Chen* also provides the materials to protect the viability of the lactic acid producing bacteria in lyophilized form and the method to prepare the composition. However, *Chen* fails to disclose the use of a meat peptone or the advantages of using same anywhere in his disclosure.

Brody discloses the biological activity of bovine κ -caseino glycomacropeptide ("GMP") for protection against toxins, bacteria and viruses and modulation of the immune system. *Brody* is focused on studies of bovine milk GMP. *Brody* fails to disclose the use of a meat peptone, especially in combination with a meat extract, according to the present claims.

Farmer discloses the use of compositions including a lactic acid bacteria for administration to the intestinal tract for inhibiting infections including Sudden Infant Death Syndrome ("SIDS"). At no place in the disclosure does *Farmer* consider the use of oral compositions having meat peptones and meat extracts, let alone compositions having meat peptones and meat extracts in the presently claimed volumetric amounts. Moreover, because the peptone (no description of type) and meat extract of *Farmer* are only used as a culture medium to grow bacteria and never in a composition administered to a human or an animal (see *Farmer*,

Example 1), *Farmer* fails to disclose administering to a human or animal an oral composition having a meat peptone and a meat extract.

For at least the reasons discussed above, the cited references fail to disclose or suggest each and every element of independent Claim 1. Moreover, the cited references fail to even recognize the advantages, unexpected benefits and/or properties of a method for treating the effects of infection by enterotoxin-producing pathogens in accordance with the present claims. As a result, Applicants respectfully submit that independent Claim 1, along with any claims that depend from Claim 1, are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejection of Claims 1-3 and 5-11 under 35 U.S.C. §103 be reconsidered and withdrawn.

Applicants note that Claims 12-14 have been newly added. The new claims are fully supported in the specification, for example, at page 4, line 37 to page 5, line 8. Applicants respectfully submit that Claims 12-14 should be allowed.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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